KleinTouch Pump Instructions For Use

Caution: Federal (USA) Law restricts this device to use by, or on the order of, a physician.

EC REP
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SYMBOLS

	MET LABORATORIES Classified: UL 60601-1 & C22.2 NO. 601.1 only with respect to Electrical Shock, Fire, and Mechanical Hazards Classification #E112338
	Type B applied part.
	OFF (POWER: DISCONNECTED FROM THE MAINS)
	EXPLOSION RISK IF USED IN THE PRESENCE OF FLAMMABLE ANESTHETIC.
	Caution, see instructions for details
	Waste Electrical and Electronic Equipment Directive (WEEE)
	Consult Instructions for use
	Serial Number
	Product/Reference Item Number
	Authorized representative in the European Community: EMERGO EUROPE, Molenstraat 15, 2513 BH, The Hague, The Netherlands
	Manufactured by: HK Surgical Inc, 1271 Puerta del Sol, San Clemente, CA 92673 USA www.hksurgical.com, 1 (800) 909-0060, 1 (949) 369-0101

REAR PANEL LABEL

KleinTouch Pump
Manufactured By:
HK Surgical Inc
1271 Puerta del Sol, San Clemente, CA 92673 USA
www.hksurgical.com
1 (800) 909-0060, 1 (949) 369-0101
100 - 240 VAC
50/60 HZ
2.5 A
SN XXXXXXXX
REF KTP
For use: See Instructions
Caution: See Instructions
WEEE directive
Met Labs
Type B Applied part
EC REP EMERGO EUROPE, Molenstraat 15, 2513 BH, The Hague, The Netherlands
Classified to:
UL 60601-1 & C22.2 NO. 601.1
only with respect to
Electrical Shock, Fire,
and Mechanical Hazards
Classification # E112338
CAUTION: United States Federal law restricts this device to sale by or on the order of a physician.
CAUTION: TO REDUCE THE RISK OF FIRE, REPLACE ONLY WITH SAME TYPE 2.5 A - 250V FUSE
ATTENTION: POUR NE PAS COMPROMETTRE LA PROTECTION CONTRE LES RISQUES D'INCENDIE,
REMPLACER PAR UN FUSIBLE DE MEME TYPE ET DE MEMES CARACTERISTIQUES NOMINALES
116049-001Rev. B

KLEIN TOUCH PUMP SPECIFICATIONS:

- Maximum Motor Speed: 450RPM
- Holding Torque: 294 in-oz (2.08 N-m)
- Flow rate: Up to 1000 mL/min depending upon tubing set, connected cannula and pump speed
- Mode of operation: Toggle, Persistent, Trigger
- Power Requirements: 100-240 VAC, Inlet Hospital power cord IEC 320,
- Use only cordage terminated in hospital grade plugs to ensure power grounding.
- AC Frequency- 50 to 60 HZ single phase.
- Mains Power Input Fusing: 2.5A, 250V
- Leakage Current within IEC 60601-1
- Operation Humidity (non-condensing): ≤ 80% relative humidity up to 31°C and linearly decreases to 50% relative humidity at 40°C
- Operating Temperature: 4°C to 40°C
- Storage & Shipping Temperature: -20 to 50°C
- Protection against electric shock: Class I, Type B
- Enclosure rating: Ordinary equipment
- Display: Color Graphic LCD
- Dual Foot switches with 12 ft hose, air activated
- Dimensions: 11” x 10 ¾” x 5”
- Weight: 8.4 lbs
- Liquid ingress rating: IPO – No protection

Warning: Use only specified power cord supplied by HK Surgical

INTRODUCTION

Thank you for choosing the HK Surgical **KleinTouch Pump™.**

The KleinTouch Pump™ is a peristaltic pump using three rollers to create pumping action in a tubing set specifically designed for the KleinTouch Pump.

This manual provides instruction for operation, maintenance, and troubleshooting procedures for the HK Surgical **KleinTouch Pump**. Users should be trained in its use and applicable medical procedures.

INDICATIONS FOR USE

The KleinTouch Pump is an infiltration pump used to cause a flow of fluid from an IV bag into a patient in a manner controlled manually by a health care professional. **The KleinTouch pump is not intended to be used as an IV infusion pump**.

WARNINGS AND CAUTIONS

General Warnings and Cautions are labeled on the housing and in the manual. All warnings and cautions should be familiar to, and reviewed by, all personnel prior to a procedure. These cautions and warnings are considered essential to the safety of personnel, patients, equipment, and property.

- This device must be used by a trained professional with current knowledge regarding the use of the correct drug, the correct cannula size and the safe dosage. Orders for dosage must be by a physician and legible.
- This device is not intended for delivery within the parenchyma of an organ.
- This device is not intended for intravascular delivery.
- User must be aware of fluid level in IV bag. Empty bag will cause insufficient delivery.
- User must be aware of proper tube management to prevent leaks or pinching.
- Device should be operated in a no spray zone.
- While device is operating, sterile procedure protocol must be maintained.

If you have any questions, please contact HK Surgical at 800-909-0060 or 949-369-0101.

DANGER ANESTHETICS - Risk of Explosion if used in the presence of flammable anesthetics!

CAUTION – Risk of electrical shock. Do not open case. Refer to proper authorized personnel for servicing. Do not use the device with broken or missing parts, this may result in injury.

Tubing other than that supplied with the pump may not be used with this device because use of other tubing may cause incorrect flow rate. Per M5 Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007, the tubing used in conjunction with the KleinTouch Infiltration Pump is designed for single use only. The KleinTouch Pump will restrict reuse of disposable, sterile KleinTouch Infiltration tubing sets.

MODIFICATIONS

Modifications to any component of this device may create possible hazards and/or impair the safe use of this product during a procedure. Any requests for changes in design or use should be sent or communicated to the proper HK Surgical personnel.

INSTALLATION

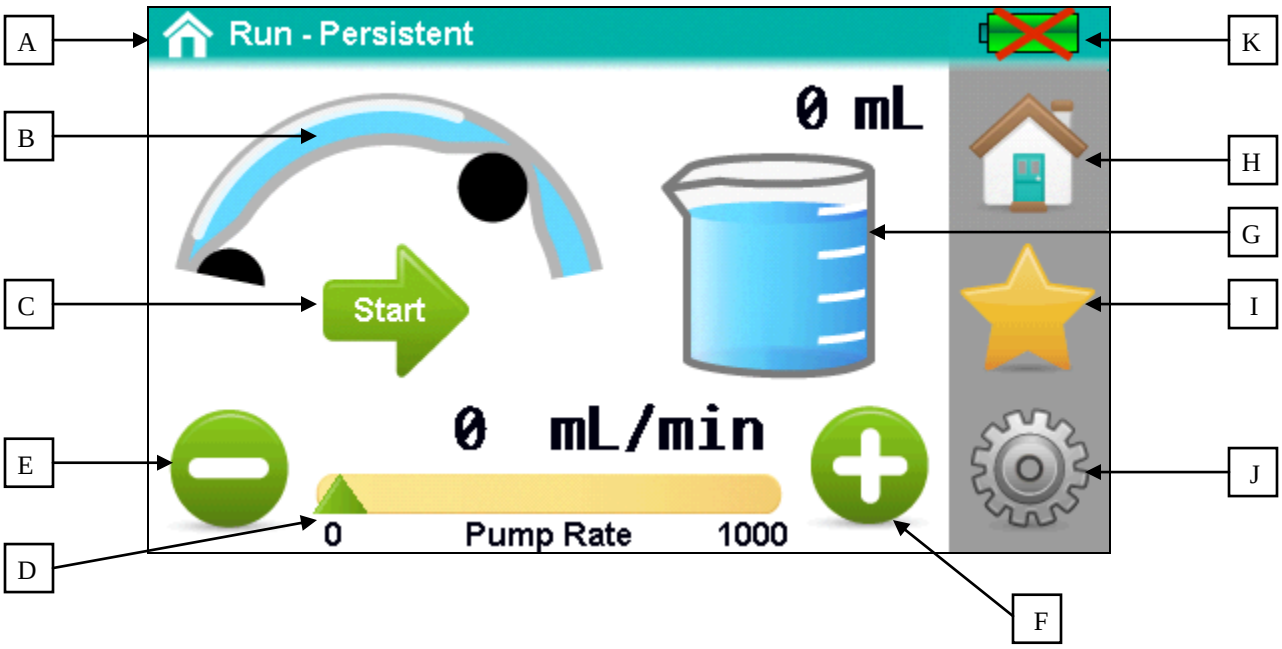
- Remove the pump and accessories from the shipping box.
- Inspect the pump and accessories to insure all components are included and undamaged.
- The shipment should include the following:
    1. One KleinTouch Pump
    2. One Power Cord (specific to your country voltage)
    3. One pneumatic foot pedal
    4. One Instruction For Use Manual (IFU)

Back up battery and additional foot pedal are available upon request. Please contact HK Surgical to order additional accessories at 800-909-0060 or 949-369-0101.

SETUP INSTRUCTIONS

1. Connect the appropriate power cord into the back of the pump.
2. Connect the pneumatic foot pedal actuator into provided ports located on the front of the pump, under the Touch Screen. Foot pedal can be inserted into any of the 3 ports. Additional ports are designed for accommodating second foot pedal for opposite side of OR table. Pump can be deactivated via the touch screen or either foot pedal.
3. The main power ON/OFF switch is located on the rear panel. Turn the power ON. When powered on, the front panel touch screen is illuminated and the rear power switch indicator light turns green.
4. The scan and load screen will appear on the touch-screen indicating the scanner is off and the pump head latch must be opened to activate the scanner.
5. The touch screen will then direct the user to scan barcode. The barcode on tubing pouch is scanned by aligning barcode with the barcode reader located between the touch screen and the foot pedal ports. **Note:** If the barcode does not scan immediately, hold barcode 4 inches in front of scanner and slowly move it toward pump.
6. When tubing has been successfully scanned, the touch screen will indicate “Accepted” and the red line will remove from the bar code.
7. If a tubing scan has been unsuccessful, an error message will appear indicating that either the barcode is damaged or the barcode has previously been scanned and is therefore not valid. Refer to Trouble Shooting guide for additional instruction if necessary.
8. After a tubing scan has been accepted, prepare to insert tube set. When facing the KTP unit the **spike side** of the tubing set is on one’s left. When the tubing is placed into the roller section, check to be certain that the flow direction is from left to right (clockwise). Insert tube set. Close pump head latch. The unit is designed to specifically function with sterile single use only Klein Touch Tubing (KT20). Tubing must be primed before use. Please refer to the Klein Touch Tubing Instructions for Use for further details.
9. Once pump head latch is closed, the home screen will be displayed. Note: In order to advance to the home screen, tubing insertion and barcode scan must be completed.
   NOTE: TIME EXPIRED - The operator must use the KTP tubing within 72 hours from scan.
10. See pages 9-20 to program specific setting fields and return to home screen to activate pump. Foot pedal will not activate unless user has returned to the home screen.

HOME SCREEN ICON DEFINITIONS



A. Current mode of operation in use

B. Directional fluid flow

C. Start arrow and stop sign - This icon can be used to start and stop the pump versus foot pedal

D. Pump rate bar controls the increase and decrease of speed

E. Minus icon decreases pump rate.

F. Plus icon increases pump rate.

G. Number above flask indicates the approximate volume of fluid delivered.

H. Home Screen icon

I. Favorites icon

J. Settings icon

K. Battery Indicator- optional battery is available for purchase.

Note:

Factory Default Settings: Language - English, Mode of Operation – Persistent

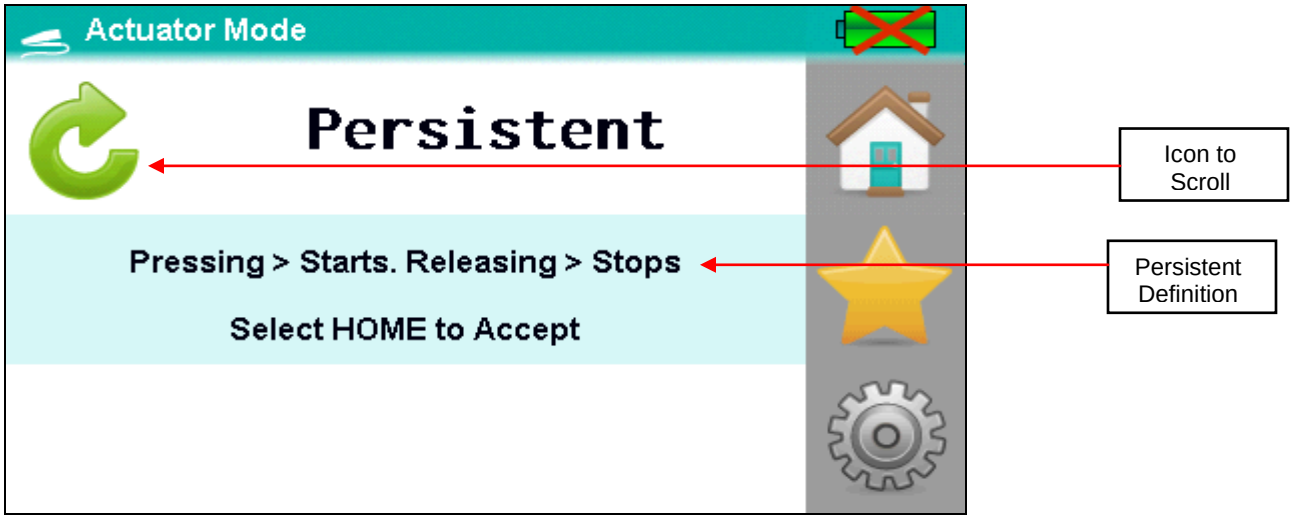
Tone – Level 3, Roller Direction - Clockwise

SETTINGS

From the home screen, press the Setting icon to begin programming the KleinTouch pump. Within the settings screen user has the capability of programming multiple fields. **Actuator** - mode of operation, **Direction** - the direction of flow, **Tone** - audio volume control, **Cannula** – cannula tuning, **Language** - language preference and **Information** - manufacturer contact details.

ACTUATOR

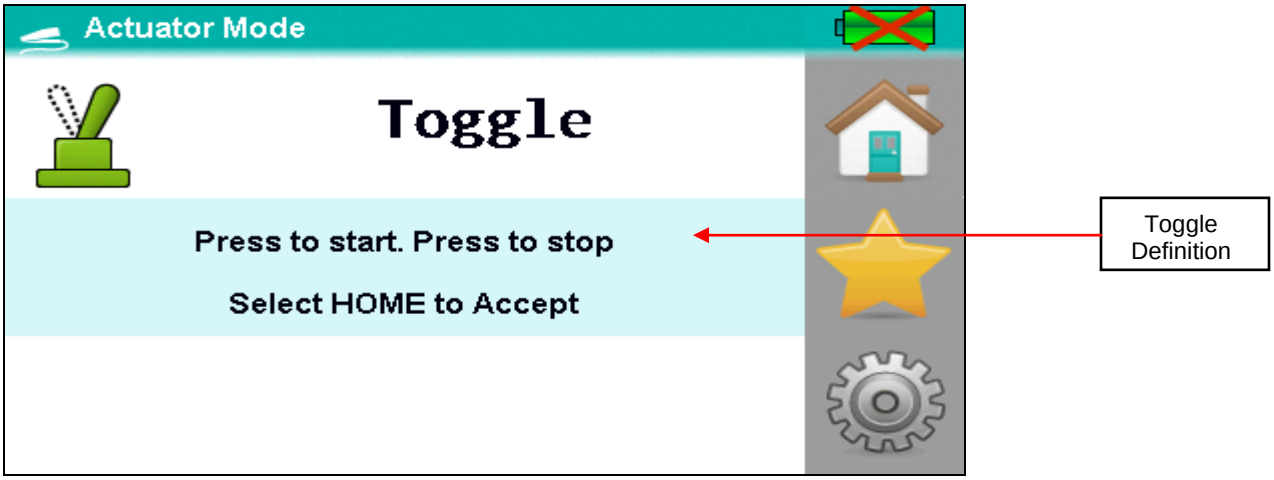
To program the mode of operation, touch the Settings icon and then the actuator icon. To change the mode of operation, touch the current icon (Persistent) shown to scroll through the three modes of operation. To save the selection, touch the home icon.



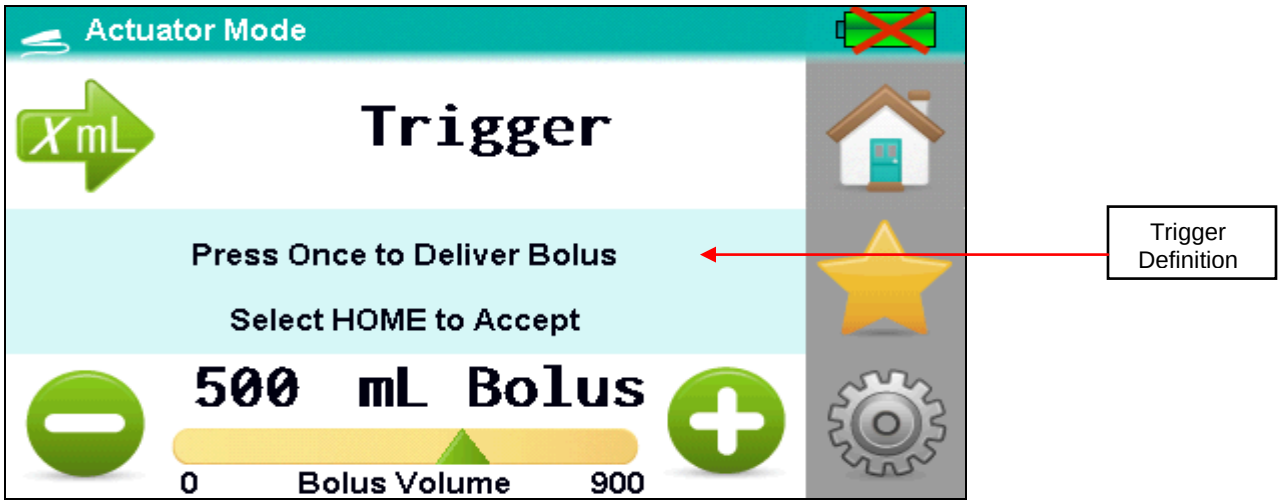
There are three modes of operation from which to choose. The modes are:

Persistent - In this mode, the foot pedal must be held down to enable operation and released to stop operation. (The factory default mode of operation is Persistent.)

Toggle - In this mode, depress foot pedal to start operation and depress again to stop the operation. Either foot pedal can start or stop operation.



Trigger- This mode will deliver a specific volume of fluid each time the foot pedal is depressed. There are two methods to select the desired bolus size. In the first method, increase or decrease the size of the bolus by touching the plus or minus icons. In the second method, increase or decrease the size of the bolus by tapping your finger on the bolus bar in the direction desired.



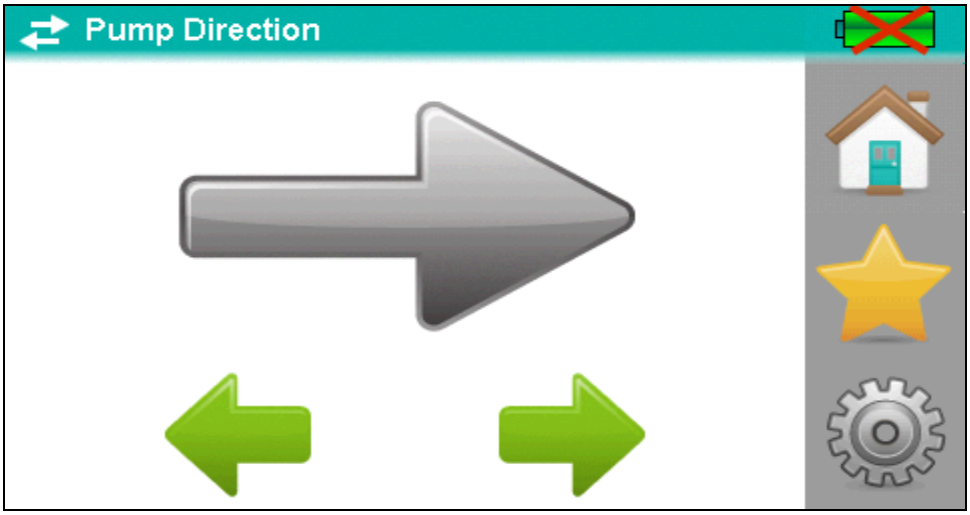
Note: Once selection has been made, touch the home screen icon to save setting and return to home screen where user will set flow rate and activate pump.

DIRECTION

To program the direction mode, touch the Settings icon and then the Direction icon. There are two modes of direction from which to choose. (The factory default mode is forward/clockwise direction).

These modes are:

1. Forward – in this mode of operation, the pump rollers will move fluid in a clockwise direction. To advance in forward direction, touch the right arrow.
2. Reverse – in this mode of operation, the pump rollers will move fluid in a counter clockwise direction. To advance in reverse direction, touch the left arrow.



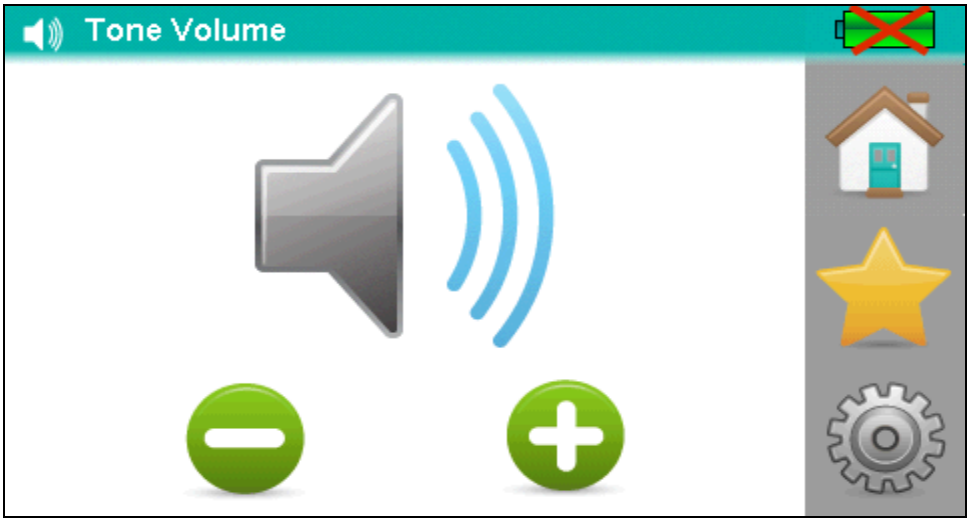
Note: Once selection has been made, touch the home screen icon to save setting and return to home screen. Foot pedal will not activate unless user is on home screen.

TONE

To program the mode of audio beeper, touch the Setting icon and then the Tone icon.

1. To increase the volume of the beeper, touch the plus icon.
2. To decrease the volume of the beeper, touch the minus icon.
3. When the minus icon is decreased to a mute level, the NO symbol Ø is overlaid on the speaker symbol.

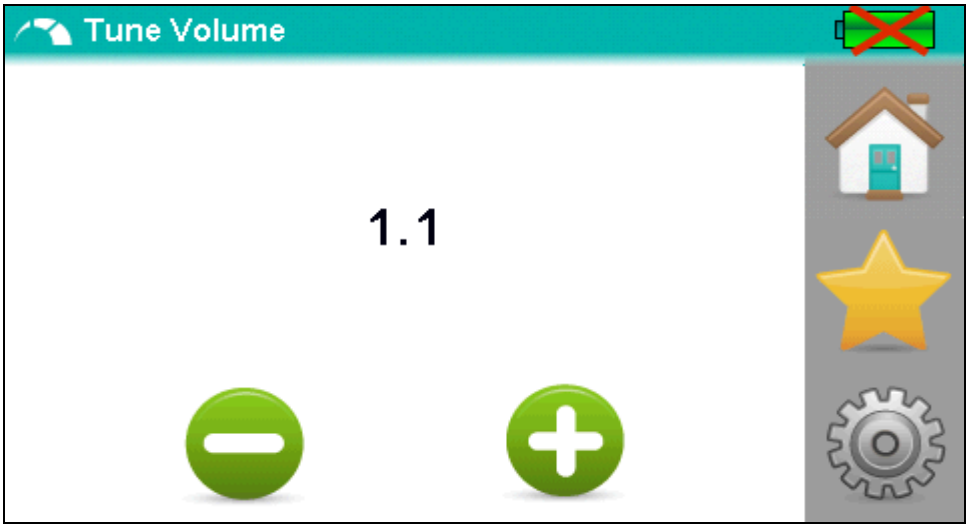
(The factory default mode is level 3)



Note: Once selection has been made, touch the home screen icon to save setting and return to home screen.

CANNULA

To program your pump and tune your specific cannula/needle of choice, use the Cannula Tuning Setting to increase the volume accuracy. To increase or decrease the setting use the plus and minus icons.



Note: Once selection has been made, touch the home screen icon to save setting and return to home screen.

The Chart below can be used as a guide to determine the appropriate cannula setting to use with your specific Infiltration Cannula.

Cannula	Target Flow Rate (ml/min)	Cannula Setting Tune Volume	Volume Error Ratio
12G Tip Monty	50	0.9	101%
12G Tip Monty	500	0.9	102%
14G Tip Monty	50	0.9	107%
14G Tip Monty	500	0.9	98%
16G Full Monty	50	0.9	107%
16G Tip Monty	50	0.9	100%
16G Full Monty	500	0.8	100%
16G Half Monty	500	0.9	104%
16G Half Monty	500	0.7	100%
16G Tip Monty	500	0.7	104%
16G Half Monty	1000	0.6	108%
16G Full Monty	1000	0.8	98%
18G Tip Monty	50	0.9	100%
18G Tip Monty	50	0.9	103%
18G Tip Monty	500	0.6	84%
18G Tip Monty	500	0.5	106%
20G needle	50	0.9	106%
20G needle	500	0.5	61%

NOTE: With the 18 gauge cannula, the operator must not run the pump at more than 500ml/min. In addition, the 20 gauge cannula should not be run at more than 50ml/min.

NOTE: The table data results are based on a single data point for each cannula optimal setting configuration.

The following conditions below yielded flow and volume accuracy within ±20% (3 standard deviations) without adjustment of the cannula setting when the source was located within 24 inches upstream of the pump head. This is a guide for determining what gauge can be used for 3 different flow rates.

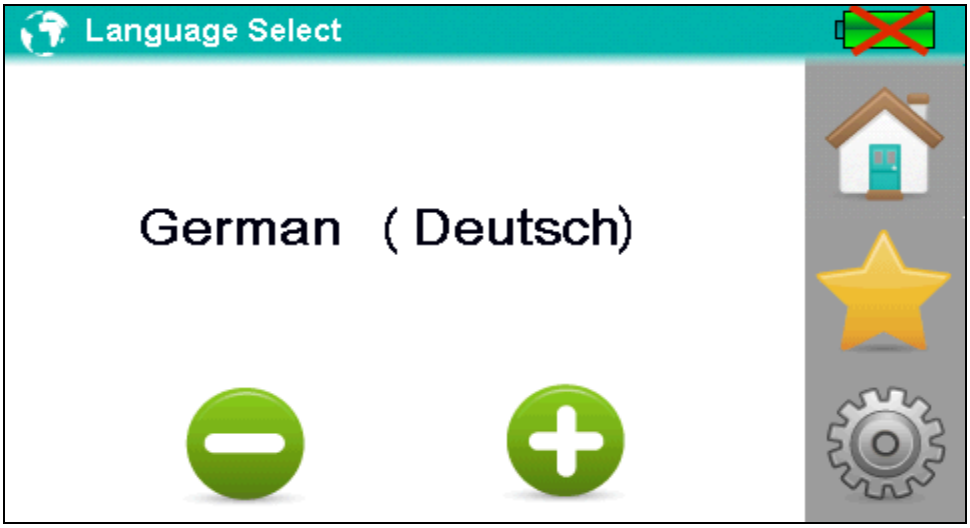
Gauge Size	Flow Rate (ml/min)		
12	50	500	1000
14	50	500	1000
16	50	500	
18	50		
20	50		

LANGUAGE

Touch the Settings icon and then the language icon to program the language of choice.

1. Use the plus and minus icons to scroll alphabetically through the language list.
2. The available languages are: Danish, Dutch, English, Finnish, French, German, Hungarian, Italian, Japanese, Norwegian, Polish, Portuguese, Spanish, Swedish, Turkish
3. Once desired language is shown, touch the home icon to save. Pump will now display all text in the selected language.

   (The factory default mode is English) (Power up default is previously programmed language)



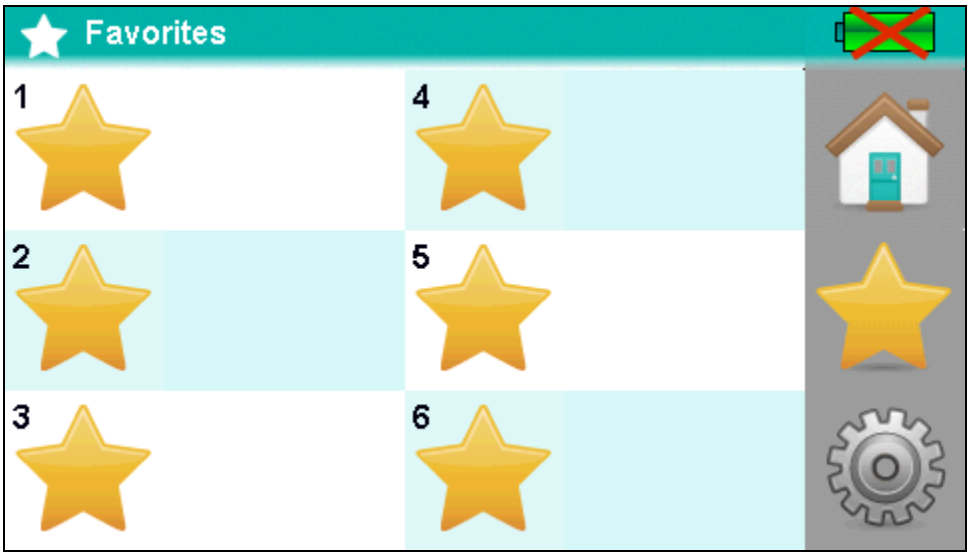
Note: Once selection has been made, touch the home screen icon to save setting and return to home screen.

INFORMATION

Touch the Setting icon and then the information icon to view manufacturer contact details.

FAVORITES SETTING

Press the star icon on the right side of the touch screen to enter the Favorite Setting Screen



There are six separate settings that can be programmed and saved as favorites on the KleinTouch Pump. The initial screen will show six blank stars indicating there are no saved favorites. Favorites are a combination of modes of operation and pumping rate.

1. Touch the star icon of the favorite to program. The text beside the star will indicate the favorite is undefined. To set a favorite, touch the star on the top left and scroll through the modes of operation until the desired selection is located. Once the mode of operation is identified, select the pump rate. To save, touch the home icon.

2. To redefine a favorites setting, touch the favorite to be changed. Modify the favorite by adjusting the mode of operation or the pump rate or both and touching the home icon to save.
3. To remove a favorite setting, touch the favorite to be changed then touch the reset icon. The setting will be cleared. To return to the home screen, touch the home icon.
4. Power up default will be previously programmed favorites.

NOTE: When operating in a favorite mode, home screen can still be used to adjust speed.

EQUIPMENT OPERATING PROCEDURES

1. The pneumatic foot pedal **or** the LCD touch screen can control the peristaltic pump when the unit main power switch is on.
2. The pump head latch must be in locked position to operate pump. Lifting the latch de-activates the pumping action. The KleinTouch Pump has a hardware lockout feature to cease motor operation if pump head cover is opened.
3. In addition to the pump not operating when pump head is opened, a dialog box will appear prompting the user to identify if this is a new patient. If this is a new patient, follow the set up instructions for installing a new sterile tubing set. If there is not a new patient the display message will state close door and you will be returned to the home screen.
4. Any of the pneumatic foot pedal ports can be used below the touch screen. All pneumatic foot pedal ports can be used to turn the pumping action on and off. The foot pedals may be operated in any sequence to activate or deactivate the pumping action.
5. Turn main power switch to off when not in use.
6. To adjust the speed of the flow rate on the home screen touch the plus or minus icon to increase or decrease or touch the bar at the appropriate location. Do not slide the bar, tap the bar as needed.

BATTERY MAINTENANCE/OPERATION

- If there is no battery added to the pump, the battery icon at the top right of the home screen will display a X over the battery symbol.
- When using the battery, operator will need to monitor the battery level.
- If a battery is installed the battery icon will be green.
- As the battery is used, the green color of the icon will decrease in correlation to the power used and will show the power remaining.
- When the icon turns red the battery needs recharging. The battery can be recharged by plugging the unit into a power outlet.
- The pump battery should be fully charged after 2 hours of use while plugged into power outlet.
- The battery should be **replaced** when the charge monitor icon shows red within 2 hours of use after being fully charged.
- The operator should be instructed that when they operate the pump on battery power, the operator needs to monitor the battery level and must plan to stop within 2 hours or when the level indicator shows red.
- Battery is UL recognized and fully enclosed within the pump.
- Electrical instruments and batteries should be disposed of in accordance with local regulations.

USER MAINTENANCE

1. No pump maintenance is required. All components are lifetime lubricated. **DO NOT lubricate.**
2. Check condition of power cord and footswitch tubing annually. Replace if cracked or worn.
3. Electrical instruments and batteries should be disposed of in accordance with local regulations.

ANNUAL PUMP MAINTENANCE

- Follow the steps below to annually check your pump for correct volume deliver:
- Prime the tubing set.
- Set the pump in Trigger mode with a 900ml target and set the pump rate to 500ml/min.
- Start the pump and a timer.
- When delivered, measure the volume delivered and calculate the rate as the measured volume delivered/time to deliver that volume in minutes. This must be within 20% of the target rate.
- The Klein Touch Pump has a suggested pump life of 8 years.

CLEANING PROCEDURE

1. Dirt, stains, and dried materials can be removed from the case by using any mild nonabrasive cleanser, such as 409 or 10% bleach.
2. The surface may then be wiped clean with a damp cloth.

TROUBLESHOOTING GUIDE

Please contact HK Surgical for assistance if the following solutions do not resolve the problem.

PROBLEM	POSSIBLE CAUSES	SOLUTION
Pump not operating	1. Power switch not on. 2. Power cord not plugged into wall outlet. 3. Power cord not plugged into unit. 4. Foot pedal not activated or start arrow not pressed. 5. Forward arrow on home screen not pressed.	1. Turn power switch to “on.” 2. Plug power cord into outlet. 3. Plug power cord into connector in rear of unit. 4. Depress foot pedal or touch start button on touch screen. 5. Press the forward arrow on the home screen.
Foot pedal will not activate pump.	1. Foot pedal actuator not connected. 2. Foot pedal broken. 3. Power switch not on.	1. Connect foot pedal actuator to port in front of unit. 2. Check for torn or broken tubing. Replace foot pedal. 3. Turn power switch to “on.”

Inadequate flow when foot pedal is pressed.	1. Speed control set too low. 2. Cannula size is too small.	1. Touch the plus icon on the home screen to increase speed. 2. Refer to the cannula setting guide under Cannula Instructions.
Tubing continues to drip after pump is stopped.	1. Gravitational flow.	1. Hang the IV bag level with the pump. 2. Depress the clamp on the tube set.
Fluid backing into IV bag.	1. Tubing installed incorrectly.	1. Facing the unit, insert tubing with the spike on the left and the luer lock on the right. 2. Ensure that the tubing is fully inserted into the pump head and that the pump head is fully closed.
Tubing does not fit securely in pump head.	1. Using tubing that is not approved HK Surgical Klein Touch Tubing.	1. Use appropriate sterile tubing set supplied by HK Surgical – KleinTouch Infiltration Tubing.
Pump is not operating in battery mode	1. Battery needs to be charged.	1. Plug unit into power outlet and battery will charge. Observe the battery indicator symbol on the home page.

APPROVALS

SAFETY: MET LABS tested per UL Standards 2601-1; 2nd ed. Medical Electrical Equipment- Part 1 General Requirements for Safety

- CSA C22.2
- UL 60601-1
- EN/IEC 60601-1

EMC:

- IEC/EN 60601-1-2:2007-ED30
- JSA-JIS T0601-1-2:2002
- AS/NZ 3200.1.2:2005

TECHNICAL MANUALS

Repairs must be made by HK SURGICAL or authorized facility. No service manuals are available for this reason. Replacement disposable tubing, foot pedals and power supply cords may be purchased from:

HK Surgical, Inc.
1271 Puerta del Sol
San Clemente, CA 92673-6310
Ph: +1.800.909.0060
Fax: +1.949.369.9797

INSPECTION UPON RECEIPT OF PRODUCT

Examine shipment upon receipt for any external damage. Note any damage on the shipping receipt. The merchandise is carefully packaged to prevent shipping damage; however, our responsibility ends with the delivery of the shipment in good condition to the transportation company.

If the product package is damaged, retain all packaging materials, notify the transportation company and make a notation on the shipping receipt.

REPORTING CONCEALED SHIPPING DAMAGE OR MISSING PARTS

Please set up and operate the product as soon as possible to discover any hidden shipping damages. If damage is revealed, contact the carrier to have an agent inspect the damage. Most freight and shipping companies have a limited time period for accepting this type of damage claim. Contact your carrier immediately. The carrier reserves the right to refuse any loss or concealed damage claim made beyond that time. HK SURGICAL is not responsible for the collection of claims or replacement of damaged merchandise. We will aid you in any way possible to achieve a satisfactory outcome for your damage claim. FILING AND HANDLING THE CLAIM IS YOUR RESPONSIBILITY.

Be sure to keep all original packaging materials in the event that the items need to be returned.

RETURN PROCEDURE

Contact HK Surgical prior to returning any merchandise to obtain a RMA approval number. No returns will be accepted unless a RMA number has been issued by HK Surgical. Have the following information available at that time.

- Invoice or relevant information to invoice.
- Contact person and phone number.
- Product information, number.
- Serial number
- Reason for return.

If the product has been exposed to any bio-hazardous materials or used in surgery or surgical related area, it must be CLEANED and STERILIZED and HAVE A WRITTEN STATEMENT OF CONFORMATION OF STERILITY accompanying the returned product.

Important Note: Please retain your Klein Touch Pump Shipping box – all pump returns to HK Surgical **must** be shipped in the specifically designed Klein Touch Pump box.

Please refer to the **HK Surgical Product Return Policy** included with your order for additional terms and conditions

WARRANTY

HK Surgical products are manufactured to be used by qualified medical personnel trained and skilled in their use.

HK Surgical products are warranted to be free from manufacturing defects in materials and workmanship for a period of **one year** from date of purchase. HK Surgical will repair or replace, free of charge, any part, or parts that are defective in material or workmanship during that time period. Transportation charges on parts submitted for repair or replacement under this warranty must be borne by purchaser. This warranty does not apply to damages caused by misuse, mishandling, improper operation, and/or by abuse of the product. There is no other expressed Warranty including those of fitness or a particular purpose, to the extent permitted by law and all implied Warranties are excluded.

Manufactured For:
HK Surgical, Inc.
1271 Puerta del Sol
San Clemente, CA 92673-6310 U.S.A.
Ph: 800.909.0060 or +1.949.369.0101
Fax: +1.949.369.9797
www.hksurgical.com